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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/736,936	12/16/2003	Todd G. Kirchgessner	DB23 DIV1	6764

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EXAMINER	
CHERNYSHEV, OLGA N	
ART UNIT	**PAPER NUMBER**
1649	

DATE MAILED: 11/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/736,936	KIRCHGESSNER ET AL.	
	Examiner	Art Unit	
	Olga N. Chernyshev	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *5,6 and 9-16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *5,6 and 9-16* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Formal matters

1. The Art Unit location of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1649.

Election/Restrictions

2. Claims 5, 6 and 9-16 are pending in the instant application.

3. Claim 5 is objected to as reciting an improper Markush Group. MPEP 803.02 states that

> "Since the decisions in In re Weber, 580 F.2d 455, 198 USPQ 328 (CCPA 1978) and In re Haas, 580 F.2d 461, 198 USPQ 334 (CCPA 1978), it is improper for the Office to refuse to examine that which applicants regard as their invention, unless the subject matter in a claim lacks unity of invention. In re Harnish, 631 F.2d 716, 206 USPQ 300 (CCPA 1980); and Ex parte Hozumi, 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984). Broadly, unity of invention exists where compounds included within a Markush group (1) share a common utility, and (2) share a substantial structural feature disclosed as being essential to that utility."

Applicant is advised that claim 5 is an improper Markush claims because the plurality of amino acid sequences recited in this claim lack a common utility, which is based upon a shared structural feature lacking from the prior art. Each of these proteins are independent and distinct chemical compounds lacking either a common structural property which distinguishes them as a group from structurally related compounds of the prior art or which provides them with a common utility which is lacking from those prior art proteins.

4. Therefore, restriction to one of the following inventions is required under 35 U.S.C. 121:

I to VI. Claims 5, 6, 11 and 15, in so far as they are drawn to **any one** of the six isolated polypeptide sequences recited therein, classified in class 530, subclass 350. For example, Invention I consists of claims 5, 6, 11 and 15 only in so far as they encompass an isolated polypeptide of SEQ ID NO: 2. Invention VI consists of claims 15, 6, 11 and 15 only in so far as they encompass an isolated polypeptide of SEQ ID NO: 12.

VII to XII. Claims 9-10, in so far as they are drawn to an antibody that binds to **any one** of six polypeptide sequences recited therein, classified in class 530, subclass 387.1, for example.

XIII to XVIII. Claim 12, in so far as it is drawn to a method for identifying a ligand capable of binding to **any one** of six polypeptide sequences recited therein, classified in class 435, subclass 7.1, for example.

XIX to XXIV. Claim 13, in so far as it is drawn to a method for identifying a substrate which is capable to be transported by **any one** of six polypeptide sequences recited therein, classified in class 424, subclass 9.1, for example.

XXV to XXX. Claim 14, in so far as it is drawn to a method of delivering to an organ a molecule that expresses **any one** of six polypeptide sequences recited therein, classified in class 514, subclass 44, for example.

XXXI to XXXVI. Claim 16, in so far as it is drawn to a method for modulating the activity of a polypeptide of **any one** of six amino acid sequences recited therein, classified in class 436, subclass 501, for example.

5. The inventions are distinct, each from the other because of the following reasons:

6. The isolated proteins that are inventions I to VI are six different chemical compositions each of which can be made and used without each other. Lack of unity is shown by the fact that these six different compositions lack a common utility based upon a shared structural feature lacking from the prior art.

Inventions I to XII are independent and distinct, each from each other, because they are products which possess characteristic differences in structure and function and each has an independent utility that is distinct for each invention which cannot be exchanged. Furthermore, the products of Inventions I to XII do not reflect a single inventive concept because they do not share a common feature or combination of features that distinguishes them as a group from prior art.

The polypeptides of Groups I to VI and the antibodies of Groups VII to XII are patentably distinct for the following reasons: while the inventions of both Groups I-VI and VII-XII are polypeptides, in this instance, a polypeptide of Groups I-VI is a single chain molecule that functions as a transport protein, whereas the polypeptide of Groups VII-XII encompasses antibodies including IgG which comprises 2 heavy and 2 light chains containing constant and variable regions, including framework regions which act as a scaffold for the 6 complementary determining regions (CDRs) that function to bind an epitope. Thus, the polypeptides of Groups I-VI and the antibodies of Groups VII-XII are structurally distinct molecules; any relationship between a polypeptide of Groups I-VI and an antibody of Groups VII-XII is dependent upon the correlation between the scope of the polypeptides that the antibody binds and the scope of the antibodies that would be generated upon immunization with a polypeptide.

In this case, the polypeptides of Groups I-VI are structurally unrelated large molecules which contain potentially hundreds of regions to which an antibody can bind, whereas the antibody of Groups VII-XII is defined in terms of its binding specificity to a small structure within the disclosed SEQ ID NO. Thus, immunization with the polypeptide of Groups I-VI would result in the production of antibodies outside the scope of Groups VII-XII. Furthermore, searching the inventions of Groups I-VI and Groups VII-XII would impose a serious search burden because both groups require different searches. An amino acid search of the full-length protein is necessary for a determination of novelty and unobviousness of the protein. However, such a search would not necessarily determine novelty and unobviousness of the antibodies. Furthermore, antibodies which bind to an epitope of a polypeptide of Groups I-VI may be known even if a polypeptide of Group I is novel. In addition, the technical literature search for the polypeptides of Groups I-VI and the antibodies of Groups VII-XII is not coextensive, e.g. antibodies may be characterized in the technical literature prior to discovery of, or sequencing of, their binding target.

7. Inventions XIII to XXXVI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case are directed to different methods that recite structurally and functionally distinct elements, are not required one for the other, achieve different goals, and therefore constitute patentably distinct inventions. The instant specification does not disclose that these methods would be used together. The methods of Groups XIII to XXXVI are all unrelated as they comprise distinct steps and utilize different products which demonstrates that each method has a different mode of

operation. Each invention performs this function using a structurally and functionally divergent material. Moreover, the methodology and materials necessary for performing assays and treatment of diseases differ significantly for each of the materials. Searching the inventions of Groups XIII to XXXVI together would impose serious search burden. The inventions of Groups XIII to XXXVI have a separate status in the art as shown by their different classification. Moreover, in the instant case, the searches for each claimed method are not coextensive. Prior art which teaches a method of Groups XIII to XVIII would not necessarily be applicable to the methods of Groups XXV to XXX, for example. For these reasons the Inventions XIII to XXXVI are patentably distinct.

8. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, recognized divergent subject matter and non-coextensive literature searches, which also includes searching different electronic databases, restriction for examination purposes as indicated is proper.

9. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

10. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

11. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Olga N. Chernyshev whose telephone number is (571) 272-0870. The examiner can normally be reached on 8:00 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet L. Andres can be reached on (571) 272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Olga N. Chernyshev, Ph.D.
Primary Examiner
Art Unit 1649

November 22, 2005